1 Amend 17 Cal. Code of Regs. section 100607 to read:

§ 100607. Access Requirements for Products Developed by Grantees.

- (a) A Grantee, a Collaborator or an Exclusive Licensee that is commercializing a Drug, as defined in Title 17, California Code of Regulations, section 100601, subdivision (i), that resulted in whole or in part from CIRM-Funded Research must submit a plan to afford access to such a Drug to Californians who have no other means to purchase the drug.
- (b) A Grantee, a Collaborator or an Exclusive Licensee that commercializes a Drug must submit the access plan described in subdivision (a) of this regulation to CIRM, within 10 business days following final approval of the drug by the federal Food and Drug Administration, unless, within that timeframe, the Grantee, Collaborator or Exclusive Licensee seeks an extension from CIRM. If CIRM grants an extension, the access plan must be submitted no later than 30 business days following final approval of the drug by the federal Food and Drug Administration.
- (c) The access plan must be consistent with industry standards at the time of commercialization accounting for the size of the market for the Drug and the resources of the Grantee, the Collaborator or its Exclusive Licensee. Grantees, Collaborators and/or their Exclusive Licensees shall have the burden of establishing that the proposed access plan satisfies the requirements of this Section.
- (d) The access plan shall be subject to the approval of CIRM after a public hearing conducted by CIRM that provides for receipt of public comment. CIRM may adopt appropriate procedures to protect proprietary information submitted by Grantees, Collaborators and Exclusive Licensees in connection with said public hearing. Approval shall not be unreasonably withheld. Overall, CIRM shall not require that proposed Access plans exceed industry standards for such plans at the time of commercialization in California.

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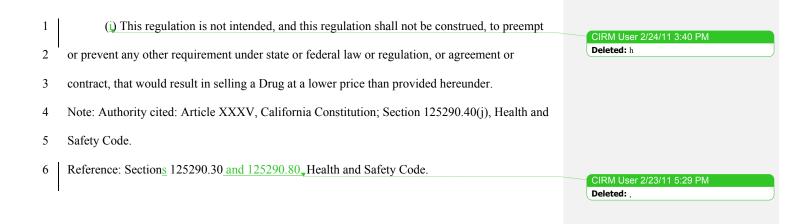
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Deleted: no fewer than 90 calendar days prior to the time the Drug is commercialized in California, unless CIRM agrees to shortened time

1	(e) Access plans approved hereunder shall make Grantees, Collabor	ators and Exclusive	CIRM User 2/23/11 5:24 PM
2	Licensees that commercialize a Drug responsible only for providing the Drug	Deleted:	
3	herein shall require the Grantee, Collaborator or Exclusive Licensee to be r	esponsible for any	
4	costs of administering the Drug nor for any associate costs of medical proce	edures or protocols	
5	for the Drug therapy, nor for any costs for attendant care.		
6	(f) The Independent Citizens Oversight Committee ("ICOC") may v	vaive the requirement	
7	in subdivision (a) of this section if the ICOC determines, after a public hear	ing, that in the	
8	absence of the waiver, development and broad delivery of the drug will be	unreasonably	
9	hindered or that the waiver will provide significant benefits that equal or ex	ceed the benefits that	
10	would otherwise flow to the state pursuant to subdivision (a) of this section.		
11	(g) A Grantee, Collaborator, or an Exclusive Licensee that is comm	ercializing the Drug	CIRM User 2/24/11 3:40 PM
12	must provide a Drug, that resulted in whole or in part from CIRM-Funded I	Research, at a price as	Deleted: f
13	provided in the California Discount Prescription Drug Program (commenci	ng with California	
14	Health and Safety Code section 130500) (or a successor statewide prescript		
15	program) to eligible Californians under said program.		
16	(h) A Grantee, Collaborator or its Exclusive Licensee that is comme	rcializing the Drug	CIRM User 2/24/11 3:40 PM
17	must sell a Drug, that resulted in whole or in part from CIRM-Funded Rese	arch, and which is	Deleted: g
18	purchased in California with Public Funds (as defined in Title 17, California Code of		
19	Regulations, section 100601, subdivision (q)) at any benchmark price described in the California		
20	Discount Prescription Drug Program or a successor statewide prescription drug discount		
21	program.		
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